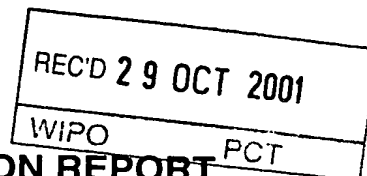



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



13

Applicant's or agent's file reference H1-108PCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/04895	International filing date (day/month/year) 21/07/2000	Priority date (day/month/year) 23/07/1999	
International Patent Classification (IPC) or national classification and IPC C12N15/12			
Applicant HELIX RESEARCH INSTITUTE et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 12/02/2001		Date of completion of this report 25.10.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Halle, F Telephone No. +49 89 2399 8537	



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP00/04895

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-23 as originally filed

Claims, No.:

1-16 as originally filed

Drawings, sheets:

1/1 as originally filed

Sequence listing part of the description, pages:

1/27-27/27, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

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- ☐ the description, pages:
 - ☐ the claims, Nos.:
 - ☐ the drawings, sheets:
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):
- (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*
6. Additional observations, if necessary:
see separate sheet

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-16(partly).

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-16(partly).

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

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1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-16
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations **see separate sheet**

Point I.6

1. The application contains sequence listing sheets 1/27-27/27.

Point III

2. The following comments only apply to the subject-matter of the claims searched according to the International search report, i.e. claims 1-16 (partly) corresponding to the first group of inventions relating to an isolated polynucleotide comprising SEQ ID NO:1 and/or encoding the polypeptide of SEQ ID NO: 2 or homologs thereof and the corresponding polypeptides, peptides, antibodies, probes, antisense molecules, methods of synthesis and methods of detection.
The claims not searched according to the International search report, i.e. claims 1-16 (partly) corresponding to the remaining groups of inventions 2 to 4 will not be the subject of international preliminary examination (Rule 66.1(e) PCT).

Point V

3. In this report it is referred to the following documents:

D1: Database EMBL, Acc. No. AA 631 935

D2: WO 99/20750

4. Having regard to the prior art D1 and D2, the subject-matter of claims 1-16 (partly) corresponding to the first group of inventions (see item 2 above) appears to be novel and to involve an inventive step. Said subject-matter is based on the more specific polynucleotide sequence defined as SEQ ID NO:1 and the polypeptide sequence defined as SEQ ID NO: 2 which are not anticipated by the prior art.

Although said subject-matter may be considered as novel an inventive, it does not appear to be sufficiently defined (Article 6 PCT). For example, in claim 1, part (a), it is referred to a coding region of a nucleotide sequence without specifying the function or the nature of the encoded protein. The same remark applies to claim 2 where it is referred to a partial peptide of the protein of claim 2. Furthermore, the wordings "a coding region of" or "a partial peptide of" do not enable the skilled

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

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person to determine with certainty which technical features are necessary to perform the invention according to the matter for which protection is sought.